K073667
pg 1 of 2

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: October 29, 2007

NOV 19

1. Submitter:

Name:	Taewoong Medical Co., Ltd. 1-5 Gomak-ri, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Republic of Korea 415871
Contact:	J.H. Nam /Director Phone +82 31 996-0641

2. Device:

Proprietary Name:	Niti-S Biliary Stent
Common Name:	Biliary Stent
Classification Name:	Biliary Catheter
Classification:	21 CFR 876.5010
Product Code:	FGE
Third Party Reviewed:	NO

3. Predicate Device:

1) Zilver Biliary Stent System USW, K040930
2) Wallstent RX Biliary Endoprostheses, K012752
3) Niti-S Stent & Introducer, Model Esophageal, K041648

4. Description:

The proposed Niti-S Biliary Stent consists of an implantable metallic stent and a flexible introducer system. The stent is a rigid, flexible, and expandable tubular device made of a Nitinol wire that is intended to be implanted to restore the structure and/or function of the biliary. This device also includes the introducer. Upon deployment, the stent imparts an outward radial force on the luminal surface of the duct to establish patency. There are 2 different types of introducers; percutaneous or endoscopic. The Stent is available in two diameters (8, 10mm), and eight lengths (40mm, 50mm, 60mm, 70mm, 80mm, 90mm, 100mm, 120mm) of Nitinol Wire.

K073667
p.3 of 82

5. Indications for use:

The Niti-S Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

6. Technological Characteristics:

The proposed Niti-S Biliary Stent is a Nitinol, self-expanding Nickel Titanium alloy (Nitinol) mounted on an introducer. There are two types; Percutaneous and Endoscopic. The Stent is available in two diameters (8, 10mm), and eight lengths (40mm, 50mm, 60mm, 70mm, 80mm, 90mm, 100mm, 120mm). Preference and individual patient condition and/or anatomy will determine the appropriate type and size.

7. Performance Data:

Laboratory testing regarding characteristics was performed on Niti-S Biliary Stent to verify its safety and performance. A biocompatibility assessment was performed on the patient contact materials of Niti-S Biliary Stent.

8. Conclusions:

Taewoong Medical Co., Ltd. concludes that the Niti-S Biliary Stent is safe and effective and substantially equivalent to the predicate devices.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2008

Taewoong Medical Co., Ltd.
c/o Ms. Cathryn N. Cambria
Consultant
Arkin Consulting Group, LLC
5536 Trowbridge Drive
DUNWOODY GA 30338

Re: K073667
Device Name: Niti-S Biliary Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: September 9, 2008
Received: September 11, 2008

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Gunnarsdottir for

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073667

Device Name: Niti-S Biliary Stent

Indications For Use: Niti-S Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073667